REMARKS/ARGUMENTS

Status of the Claims

In the Office Action mailed July 14, 2011, claims 1, 2 4-6, 8-12, 14, 15-17 and 18 were pending in the application. Claims 1, 8-10, 17, and 18 are amended. Claims 19-26 have been added. No new matter has been added by these amendments. Applicants respectfully request reconsideration of this application as amended.

Interview Summary

The undersigned thanks Examiner Bouchelle for the telephone interview conducted on November 15, 2011. A summary of the telephone interview was submitted to the patent office on November 29, 2011.

Claim Amendments

Claim 1 has been amended to refer to a system for delivery of a desired volume of fluid in a lipoplasty procedure. Similarly, claim 10 has been amended to refer to a method for delivery of a desired volume of fluid in a lipoplasty procedure. These amendments are being made to focus these claims on lipoplasty procedures. Additionally, newly added claims 19-23 are directed to systems for delivering fluid to an implantable device comprising a breast implant or a sizer; and newly added claims 24-26 are directed to methods for delivering fluid to an implantable device comprising a breast implant or a sizer.

Rejections Under 35 U.S.C. §112

Claim 10 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out a distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 10 to refer to a lipoplasty procedure consistently throughout the claim. Applicant respectfully requests withdrawal of this rejection.

Rejections Under 35 U.S.C. §103

Claims 1, 2, 4, 5, 9, 10, 11, 15 and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,319,221 to Savage et al. ("Savage") in view of U.S. Patent No. 5,178,606 to Ognier et al. ("Ognier"). Applicant respectfully traverses this rejection because the references, alone or in combination, do not teach all of the features of the pending claims.

Savage describes methods and systems for measuring fluid retention in a patient when fluid is continuously introduced into, and withdrawn from, a patient. *See Savage, col. 3, lns. 1-6.* Savage teaches that the fluid retention, or loss, in a patient is determined by weighing fluid introduced into the patient to produce a fluid-in amount, weighing fluid collected from the patient to produce a fluid-out amount, and calculating a difference. *See id.* Although the Savage system measures the amount of fluid introduced into a patient, the system does not provide for delivering a desired volume of fluid. Rather, the system described in Savage is directed to irrigation processes that provide for fluid to be continuously introduced and simultaneously removed from the patient. *See Savage, col. 3, lns. 9-17.*

Applicants point out that Savage describes a number of systems, most of which do not utilize a pump for delivering fluid to a patient and instead use gravity to deliver fluid to a patient. *See Savage, FIGS. 1 and 10.* The only embodiment that appears to utilize a pump for direct delivery of fluid to a patient is shown in FIG. 9. Savage does not teach or suggest that the pump (306) is a peristaltic pump that can deliver a desired volume ranging from 100 ml to 5000 ml at rates selected by a user as recited in claim 1. The fluid is continuously introduced at a set delivery pressure. *Savage, col. 11, lns. 1-3.* Savage does not teach or suggest that its system is designed to deliver a desired volume of fluid. Claim 1 is therefore distinct from Savage for at least this reason.

Furthermore, Savage teaches against the delivery of a desired volume of fluid. The system of Savage, as noted above, is intended to be used in surgical procedures where fluid is continuously delivered to a patient. A key concern for these types of system is to monitor the pressure within a patient to ensure that it does not reach unsafe levels. Indeed, Savage specifically states that "[t]he pump preferably has appropriate flow capability and safety features to prevent unsafe pressure (e.g., intra-uterine pressure)." *Savage, col. 10, lns. 65-67.* Delivering a desired volume of fluid to a patient may result in unsafe pressures, which

Savage's system is specifically designed to prevent. For this reason, a person of ordinary skill in the art would be guided away from modifying the system of Savage to deliver a desired volume of fluid.

Ognier teaches methods and devices similar to Savage. Ognier describes "an irrigation and aspiration apparatus for endoscopic surgery." *Ognier, col. 2, lns.* 26-27. Ognier describes controlling the flow rate (not the volume) of fluid delivered by a peristaltic pump to avoid excessive pressure. Ognier states that "[t]he peristaltic pump is advantageously driven under the control of both the manual means for regulating the flowrate and automatic stop means in the case of excess pressure in the cavity." *Ognier, col. 2, lns.* 26-27. Much like Savage, Ognier is focused on controlling the flow rate of fluid to avoid excess pressure in the cavity, and is not designed for delivering a desired volume of fluid.

Ognier also fails to teach "a processor for processing the electrical output from the strain gauge from time-to-time to determine the volume of fluid delivered for the lipoplasty procedure, wherein output from the processor is not electronically connected to the peristaltic pump to adjust the speed of the peristaltic pump during delivery of the sterile fluid, and wherein determination of the volume of fluid delivered is not affected by a change in the one or more rates during delivery of the sterile fluid," as recited in claim 1, and teaches away from such a system. In the system of Ognier, the control means must be electronically connected to the pump in order to stop the pump if the pressure exceeds a threshold level. As stated by Ognier, "the control means 32 also have [sic] a connection 34 to the means 28 for controlling the rotational speed of the pump, in order to stop the letter in the event of an excess pressure threshold (about 50mm/Hg) being exceeded in the cavity 2." *Ognier, col. 4, lns. 8-12.* Accordingly, a person of skill in the art would not modify the system described in Ognier with the feature "wherein output from the processor is not electronically connected to the peristaltic pump to adjust the speed of the peristaltic pump during delivery of the sterile fluid," recited in claim 1, because this would not allow the pump to be stopped if the pressure exceeds a threshold level.

For at least the reasons described above, the combination of Ognier and Savage do not render obvious claim 1. Furthermore, claims 4-6, 8, and 9 depend upon claim 1 and are allowable for at least the same reasons. Independent claims 10, 19, and 24 and their dependent

claims (11, 14, 15, 17, 18, 20-23, 25, and 26) recite similar features as claim 1 and they are therefore also patentable over Ognier and Savage.

Claims 5, 8, 14 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Savage as applied to Claim 1 and 10, and further in view of U.S. Patent No. 5,399,160 to Dunberger et al. ("Dunberger"). Claim 12 was rejected under 35 U.S.C. §103(a) as being unpatentable over Savage in view of Ognier as applied to Claim 1 and 10 above, and further in view of U.S. Patent No. 5,549,672 to Maddock et al. ("Maddock").

As noted above, claims 5, 8, 12, 14 and 17 depend upon claims 1 or 10. They are therefore allowable for at least the same reasons as noted above. Furthermore, Dunberger and Maddock do not compensate for the deficiencies in Savage and Ognier. Indeed, like Savage and Ognier, Dunberger describes a tubing set and irrigation system that are useful in irrigating a surgical site, such as during arthroscopic procedures. *See Dunberger, col. 3, lns. 63-65.* Dunberger discloses the use of a compliant tubing set that expands and contracts to control fluid pressure. *See Dunberger, col. 9, lns. 43-55.* Claims 5, 8, 12, 14 and 17 are therefore also patentable over the combination of Savage, Ognier, Dunberger, and Maddock.

Objective Evidence of Nonobviousness

Based on the telephone interview with Examiner Bouchelle on November 15, 2011, two supplemental declarations from Dr. Mark Jewell are being filed under 37 CFR 1.132. As noted in the previously filed Interview Summary, during the interview of November 15, 2011, Examiner Bouchelle indicated that the previously filed declaration from Dr. Mark Jewell established that a need existed, for a long period of time, for a system and method of rapidly and accurately delivering fluids in lipoplasty procedures and to fill breast implants or sizers. Examiner Bouchelle indicated however that there was not enough information, in her opinion, to establish that the need was unsatisfied by available methods and systems.

A First Supplemental Declaration from Dr. Mark Jewell is being submitted as additional evidence that establishes that the methods and systems available prior to introduction of the claimed invention (embodied in Sound Surgical's precision fluid management system (PFMS)) did not satisfy the long felt need for rapidly and accurately delivering fluids in lipoplasty procedures. The Second Supplemental Declaration from Dr. Mark Jewell is being submitted as additional evidence that establishes that the methods and

systems available prior to introduction of the PFMS did not satisfy the long felt need for rapidly and accurately delivering fluids for filling breast implants or sizers.

The supplemental declarations provide additional support for statements made by Dr. Jewell in his previous declaration filed on February 22, 2011. The supplemental declarations include citations to articles that support Dr. Jewell statements that the need for rapidly delivering and accurately monitoring fluids in lipoplasty procedures and filling of breast implants and sizers was not satisfied by methods and systems (i.e., refillable syringes, IV bags with pressure cuffs, and IV bags with pumps) available prior to the PFMS.

Dr. Jewell notes in the supplemental declarations, which are supported by journal articles, that refillable syringes are slow at delivering fluids and potentially cause surgeon fatigue or injury. *See, Dr. Mark Jewell, First Supplemental Declaration, paragraph 8; Dr. Mark Jewell, Second Supplemental Declaration, paragraph 8.* For at least these reasons, the use of refillable syringes did not satisfy the need that existed before introduction of the PFMS.

Dr. Jewell further states that the methods and systems that use pressure cuffs or pumps and IV bags rely on line markings on the IV bags to determine the volume of fluid delivered. As noted by Dr. Jewell, these line markings are subject to inaccurate readings that can have fatal consequences. *See, Dr. Mark Jewell, First Supplemental Declaration, paragraphs 9, 11, and 14.* These systems therefore also failed to satisfy the need that existed prior to the availability of the PFMS.

Additionally, Dr. Jewell also reviewed the references cited by the patent office in rejecting the present application during its pendency. In paragraphs 17 and 18 of the supplemental declarations, Dr. Jewell states that none of the methods or systems disclosed in the cited references would satisfy the need for delivering fluid rapidly and accurately in lipoplasty procedures and filling of breast implants and sizers.

The supplemental declarations from Dr. Jewell, which are supported by published articles, establishes that the methods and systems that were available prior to availability of the PFMS did not satisfy the need that existed for rapidly and accurately delivering fluids in both lipoplasty procedures and the filling of breast implants and sizers.

Referring now to the previous declarations of Mr. Dan Goldberger and Dr. Mark Jewell, these declarations provide additional evidence showing that the PFMS is superior to methods and systems that existed before introduction of the PFMS. In particular, the previous

declarations establish that after the PFMS was publically available, at least two other systems copied the features of the claimed invention. *See Declaration of Dr. Dan Goldberger, paragraphs, 9-11; Declaration of Dr. Mark Jewell, paragraph 24.* The fact that the PFMS was copied provides additional objective evidence of nonobviousness.

As indicated in both Mr. Dan Goldberger's and Dr. Mark Jewell's declarations, these devices were only available after the PFMS was publicly available. *See Declaration of Mr. Dan Goldberger, paragraphs, 9-11; Declaration of Dr. Mark Jewell, paragraph 24.* Reference is made to Exhibit C of Mr. Dan Goldberger's declaration where information regarding one of the systems that copied the claimed invention (manufactured by M.D. Resource) is shown and described. Attached hereto as Exhibit A of this Amendment and Response is a summary of a 5(k) Premarket Notification printed from the U.S. Food and Drug Administration website. The summary indicates that a system with model LS2 and LS2DP, manufactured by M.D. Resource Corp., and used in lipoplasty procedures was cleared on July 23, 2008. The LS2 and LS2DP systems are sold with the Tumescent Measuring Device (TMD) as shown in Exhibit C of Mr. Dan Goldberger's declaration. The summary of the Premarket Notification supports the statements of Mr. Dan Goldberger and Dr. Mark Jewell indicating that these devices were introduced after introduction of the PFMS.

Applicants submit that the previously filed declarations of Mr. Dan Goldberger and Dr. Mark Jewell, the supplemental declarations of Dr. Mark Jewell filed herewith, and the other information provided to the patent office, including Exhibit A of this Amendment and Response, establish that the claimed invention satisfied a long felt need that no other method or system available at the time satisfied, and as evidenced by the copies that appeared on the market after it was publically introduced, it is superior to previously available systems.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in a condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Applicants do not acquiesce to any objection, rejection, or argument not specifically addressed herein. Rather, the Applicants believe the amendments and arguments contained herein overcome all objections, rejections, or arguments.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (303) 863-9700.

The Commissioner is hereby authorized to charge to deposit account number 19-1970 any fees under 37 CFR § 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of time is required in connection with the filing of this paper and has not been separately requested, such extension is hereby petitioned.

Respectfully submitted,

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Date: January 17, 2012

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of: William W. Cimino	Group Art Unit: 3763
Application No.: 10/600,118	Examiner: Laura A. Bouchelle
Filed: June 20, 2003	Confirmation No.: 9143
Atty. File No.: 6613-19 (previously 40206.0019US01)	

For: PRECISION FLUID DELIVERY SYSTEM AND METHOD FOR SURGICAL PROCEDURES

AMENDMENT AND RESPONSE

EXHIBIT A

5(k) Premarket Notification From the U.S. Food and Drug Administration Website

Quick Links: Skip to main page content Skip to Search Skip to Topics Menu Skip to Common Links

510(k) Premarket Notification

510 (k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search Back To Search Results

Device Classification Name	System, Suction, Lipoplasty
510(K) Number	K081593
Device Name	POWER ASPIRATOR, MODEL LS2 OR LS2DP
Applicant	MEDICAL DEVICE RESOURCE CORP. 23392 Connecticut St. Hayward, CA 94545
Contact	Mel Kimsey
Regulation Number	878.5040
Classification Product Code	MUU
Date Received	06/06/2008
Decision Date	07/23/2008
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No
Combination Product	No